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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
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In re Application of :  
Roder et al :  
Serial No. 08/983,605 : Decision on Petition  
371 Filing Date: 1 May 1998 :  
Attorney Docket No. CSHL94-03A3 :

This letter is in response to the Petition under 37 CFR 1.144, filed 20 February 2002.  
The delay in acting on this petition is regretted.

#### BACKGROUND

This application was filed on 1 May 1998 under 35 USC 371 as the national stage filing of PCT/DE96/01185, filed 27 June 1996, which claims priority to Federal Republic of Germany Application serial number 195 25 284.5, filed 28 June 1995.

A review of the file history shows that original claims 1-10 were directed to microsatellite markers (claims 1-5), a method of preparing the microsatellite markers (claims 6-8) and "use" claims for the microsatellite markers (claims 9-10). Claims 9-10 were canceled and claim 6 was amended to correct dependency by Preliminary Amendment A, filed 1 May 1998 as Paper No. 5.

In the first Office action on the merits, Paper No. 10, mailed 2 September 1999, claims 1-8 were examined and rejected under 35 USC 112, second paragraph for indefiniteness and under 35 USC 102(b) as being anticipated by Roder et al.

Applicants responded by Amendment D, Paper No. 11, filed 13 December 1999, in which a limitation directed to 233 pairs of primers, identified by SEQ ID Nos. 1-466, was added to independent product claim 1 and to independent method of preparation claim 6. Dependent Claims 2-4, 6 and 8 were also amended. Claim 5 was canceled. New claim 11 was added and made dependent upon claim 1.

In Paper No. 12, mailed 25 February 2000, claims 1-4, 6-8 and 11 were rejected under 35 USC 112, second paragraph for indefiniteness concerning the amended claims.

In response, Paper No. 13 filed 10 May 2000, claims 1, 3-4, 7, 11 were amended to clarify the claimed subject matter. New claims 12-13, dependent upon claims 3-4, were added.

In a telephone interview summary on 5 June 2000, between Examiner Bui and Applicants' representative Mr. Londa, the examiner indicated that it was not feasible for the Office to examine the 466 primer sequences in a single application as each primer pair is patentably distinct. The examiner offered to examine 10 primer pairs that Applicants elect. The examiner also explained that due to temporary technical failures of the DNA database searching capabilities, none of the sequences had been searched during the preparation of previous Office action, Paper No. 12. Applicants elected the first ten [sic, pairs of] sequences, SEQ ID Nos. 1-20, for examination on the merits.

On 1 August 2000, the Office mailed a non-final Office action, Paper no. 15 that contained a restriction requirement between Groups I-XXIV. It is noted that this restriction, though in essence proper, was set forth under 35 USC 122 (applicable to application field under 35 USC 111(a)) and not under 35 USC 121 and 372, as applicable for applications filed under 35 USC 371. In view of the telephone election, SEQ ID Nos. 21-466 were withdrawn from further consideration, 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1-4, 6-8 and 11-13 were rejected under 35 USC 101, for lacking utility, under 35 USC 112, first paragraph for lack of written description and under 35 USC 112, second paragraph for indefiniteness. No claims were allowed. SEQ ID Nos. 1-20 were deemed free of the prior art.

In response, Paper No. 17, filed 29 January 2001, applicants canceled all pending claims and added new claims 14-17, directed to a method of genotyping plants by using the primer pairs 1-466.

On 9 April 2001, the Office mailed Paper No. 18, stating that the amendment filed 29 January 2001 was not responsive, as the new claims do not read upon the elected inventions.

Applicants then filed a request for a continued prosecution application (CPA) under 37 CFR 1.53(d) on 1 May 2001, as Paper No. 19. Upon acceptance of the CPA request, the filing status of the application changed from a national stage application filed under 35 USC 371 to a US application filed under 35 USC 111.

A restriction requirement was set forth on 23 May 2001, Paper No. 20, requesting that Applicants elect a single sequence or one primer pair, for examination of dependent claims 15-16. The sequences were deemed to be patentably distinct because they are unrelated sequences.

In Paper No. 21 filed 9 July 2001, Applicants provisionally elected the same primers that had already been examined by the examiner in Paper No 15, those pairs consisting of SEQ ID Nos. 1-20. Applicants also stated that should generic claim 14 become allowable, the entire of scope of claim 15 (including all 233 pairs) should be retained. Applicants noted that claim 16 was already limited to primers consisting of SEQ ID Nos. 1-20.

It is pointed out that election of ten pairs of primers was not a proper response to the restriction requirement. The restriction requirement had required applicants to elect one pair of primers.

Nevertheless, in Paper No. 22, mailed 2 August 2001, the Examiner treated Applicants' response as a election of SEQ ID Nos. 1 and 2 with traverse. The restriction requirement was supported by the statement that "additional searches of 18 more nucleotide sequences requires extensive searches in all nucleic acid databases. Review of these additional searches is prima facie evidence of burden which is not rebutted." The restriction requirement was deemed proper and made Final. Only SEQ ID Nos. 1 and 2 were examined. Claims 14-17 were rejected under 35 USC 112, second paragraph for indefiniteness. Claims 14 and 17 were rejected under 35 USC 103(a) a being obvious over Morgante et al and Mets et al. Claims 15 and 16 as directed to SEQ ID Nos. 1 and 2 were deemed free f the prior art.

In a telephone interview on 31 January 2002, Examiner Chakrabarti spoke with Applicants' representative David Kin concerning the Morgante reference and the effective filing date of the application, which applicants assert as 28 June 1995.

In Paper No. 25, filed 19 February 2002, applicants amended claims 14-16.

On 20 February 2002, this petition was filed as Paper No. 24. Regretfully, the petition was not promptly forwarded for consideration.

In the final Office action, Paper No. 26, mailed 11 April 2002, the rejection of claim 14 and 17 under 35 USC 103(a) was maintained. Claims 15 and 16 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claims and any intervening claims. This objection was based upon the absence of any prior art teaching or suggesting the primers having SEQ ID Nos. 1 and 2.

In the petition filed 20 February 2002, as Paper No. 24, applicants have argued that the 10 primer pairs elected and acknowledged by Examiner in Paper No 15 are not an undue burden. The petition also points to the examiner's interview summary in which the examiner states that she would be willing to examine 10 primer pairs (20 sequences) that applicants elect. Applicants then acknowledge the election of SEQ ID Nos. 1-2. In addition, applicants provisionally elect an additional eight primer pairs that comprise

SEQ ID Nos. 27, 28; 93, 94; 129, 130; 203, 204; 277, 278; 315, 316; 345, 346; 361, 362; 383, 384; 397 and 398. It is noted that ten, not eight, additional primer pairs were provisionally elected in the petition.

## DISCUSSION

The application, file history and petition have been carefully considered. The petition presents the following two points that will be addressed below:

- (1) searching the additional primer pairs would not present an undue burden, because MPEP 804.04 states that a reasonable number of such nucleotide sequences to be claimed; ten pairs of sequences are a reasonable number and because the Examiner examined twenty sequences (Paper Nos. 14 and 15) and
- (2) the new request for examination of SEQ ID Nos. 1 and 2 in addition to 8 [sic, 10] primer pairs: SEQ ID Nos. 27, 28; 93, 94; 129, 130; 203, 204; 277, 278; 315, 316; 345, 346; 361, 362; 383, 384; 397 and 398.

The review of the file history has also identified several missteps that require correction and will be pointed out during the text of this discussion.

Regarding applicants' first point, the restriction requirement set forth in Paper No. 20, limiting applicants to one pair of primers was in error for the following reasons.

The restriction was based upon the incorrect premise that methods of using the 233 primer pairs would create undue burden. In the instant application, no additional burden of search would be encountered, since the Office has already accepted 10 pairs of primers SEQ ID NOS 1-20, searched SEQ ID Nos. 1-10 and indicated claims limited to SEQ ID NOS 1-20 as allowable.

An additional omission in the restriction requirement: it did not appropriately identify and treat the linking claims 14 and 17. The restriction requirement, though correct, was incomplete with respect to the formalities, because it did not include Form paragraph 8.12, which should have stated:

Claim 14 link(s) inventions 1 (SEQ ID Nos. 1-20) and Inventions 2-213.  
The restriction requirement among the linked inventions is subject to the non-allowance of the linking claim(s), claim 14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Turning now to applicants' response to the restriction requirement (Paper No. 20), applicants' provisionally elected ten pairs of primers for examination (SEQ ID Nos. 1-20). Applicants did not elect one pair of primers, as requested in the restriction requirement.

The Examiner did not adequately consider the response to the restriction requirement. This error occurred when one pair of primers (SEQ ID Nos. 1 and 2) was then picked, by the examiner, for examination. Nowhere in Paper No. 20 did applicants elect SEQ ID Nos. 1-2.

The Office will treat applicants' provisional election for methods of using primer pairs of SEQ ID Nos. 1-20 (Paper No. 21) for this application as a proper response to the restriction requirement (Paper No. 20). Although typically one pair of primers constitute a distinct and independent invention, because the product claims (ten primers pairs consisting of SEQ ID Nos. 1-20) had been searched together and found free of the art, it would present the Office no additional burden, in this application, to search and examine the methods of using the ten pairs of primers consisting of SEQ ID Nos. 1-20.

According to MPEP 819, the Office generally does not permit switching inventions. Where a continued prosecution application (CPA) filed under 37 CFR 1.53(d), is a continuation of its parent application and not a divisional, an express election made in the prior (parent) application in reply to a restriction requirement carries over to the CPA application unless otherwise indicated by applicant.

In this case, upon filing of the CPA and preliminary amendment, the category of invention was switched from products (primer pairs SEQ ID Nos. 1-20) to method of using primer pairs (SEQ ID Nos. 1-20). The status of the applications was also switched from one filed under 35 USC 371 to one filed under 35 USC 111(a). As such, US restriction practice (35 USC 121), not PCT Unity of Invention standards, apply.

With regard to the petition's second point, the untimely election of SEQ ID Nos. 27, 28; 93, 94; 129, 130; 203, 204; 277, 278; 315, 316; 345, 346; 361, 362; 383, 384; 397 and 398, will not be granted, in view of Applicants' previous election of SEQ ID Nos. 1-20 in Paper No. 21. As stated in MPEP 819.01, while applicant, as a matter of right, may not shift from claiming one invention to claiming another, the Office is not precluded from permitting a shift. It may do so where the shift results in no additional work or expense, and particularly where the shift reduces work as by simplifying the issues. (Ex parte Heritage, Pat. No. 2,375,414 decided January 26, 1944.) Accordingly, a switch to different primers at this stage in prosecution would result in additional work and expense for the Office and will not be permitted.

Two additional problems arise upon the filing of Paper No. 25 and the final Office action, mailed as Paper No. 26. The final Office action set forth in Paper No. 26 does not describe or treat the claims as they were amended by Amendment G, Paper no. 25 filed 19 February 2002. Additionally, the claims presented in Amendment G contain problematic limitations. These two inconsistencies are outlined below:

In Amendment G, Applicants have apparently amended claim 15, so that it is now directed at non-elected invention. Claim 15 recites primers other than elected SEQ ID Nos. 1-20.

It is noted that in Paper No. 26, Office action summary (PTO-326) states that it is in response to Amendment G and that claims 14-17 were indicated as rejected. In contrast, on page 5, paragraph 4, claims 15-16 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claims and any intervening claims. This objection was based upon the absence of any prior art teaching or suggesting the primers having SEQ ID Nos. 1 and 2.

In Amendment G, claims 15 and 16 were drawn to method of using primers pairs, "wherein the primer pairs are selected from at least one of the pairs SEQ ID NO. x and SEQ ID No x + 1, where x = 27, 93, 129, 203, 277, 315, 345, 361 [sic, and] 383." In contrast to the final Office action, Claim 15 does not encompass methods of using primers SEQ ID Nos. 1-20. As such, claim 15 should be withdrawn as being directed to non-elected invention.

With regard to claim 16, which depends upon claim 14, the variable "x" is not mentioned in independent claim 14. This lack of antecedent basis for variable "x" in claim 14 was overlooked in Paper No. 26. Again, claim 16 does not recite the method of using the primers SEQ ID Nos. 1-2, which the examiner has indicated as free of the prior art.

Applicants petition is granted in part. The Office grants the election of claims drawn to methods of using primers with SEQ ID Nos. 1-20. The Office does not grant applicants' request to shift inventions to methods of using any other primers.

The finality of the previous office action is withdrawn so that (1) applicants have a opportunity to present claims directed to their elected invention and (2) the examiner has an opportunity to prepare a complete, correct office action that addresses the claims as amended, with regard to the method of genotyping plants using primer pairs selected from SEQ ID Nos. 1-20.

## **DECISION**

The petition is **GRANTED-IN-PART** for the reasons set forth above.

In view of this petition decision, Applicants are given a time period of ONE (1) MONTH or THIRTY (30) DAYS from the mailing of this notice, whichever is longer, within

which to present claims directed at the elected invention, in order to avoid abandonment.  
EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR  
1.136(a). The application will then be forwarded to the examiner for action not  
inconsistent with this decision.

Should there be any questions with regard to this letter, please contact Julie Burke by  
letter addressed to the Director, Technology Center 1600, Washington DC 20231 or by  
telephone at (703) 308-7553 or by facsimile transmission at (703) 308-7230.

A handwritten signature in black ink, appearing to read "John Doll" followed by a stylized flourish.

John Doll  
TC1600 Group Director